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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,458	08/11/2000	Yumi Matsuzaki	195675US0	8810

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

12

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/636,458

Applicant(s)

MATSUZAKI ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 5-6 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 4.

- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **Detailed Action**

1. Applicant's election with traverse of Group II, claim 4, SEQ ID NO:4, in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the Office has not provided sufficient reasons or examples to support the conclusion that each sequence encodes a unique protein. Applicants assert that given the issuance of patents reading on hundreds of different protein sequences as a consequence of degrees of homology recited in the claims, it is clear that the Office does not view a unique sequence of a protein as a ground on which a restriction requirement is based. Applicants also assert that it would not be a serious burden for the Office to search all of the claimed sequences. This is not found persuasive because each of the claimed sequences represents a unique nucleotide sequence encoding a unique protein. For example, SEQ ID NO:2 differs from SEQ ID NO: 4 at residues 238, 491, numerous residues between 465-480, etc. SEQ ID NO:2 differs from SEQ ID NO:8 at numerous residues between 400-455, etc. This is not a conclusion reached by the examiner but instead is a statement of fact. As noted in MPEP 803.04, "Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121." With regard to a burdensome search, restriction to a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the

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continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application. Applicants' arguments with regard to the Office not considering unique sequences of proteins as a basis for restriction because of the homology language allowed in some issued claims in other patents is not accurate given the above citation of the relevant section of the MPEP. Therefore, restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

2. Newly submitted claims 6 and 8 are directed to an invention that is independent or distinct from the elected invention for the following reasons: Claim 6 recites a plasmid comprising SEQ ID NO:2, which is drawn to the subject matter of Group I. Claim 8 recites a plasmid comprising SEQ ID NO:6, which is drawn to the subject matter of Group III.

Since applicant has elected the subject matter of Group II (plasmid comprising SEQ ID NO:4), newly submitted claims 6 and 8 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Newly submitted claim 7 is drawn to the elected subject matter (SEQ ID NO:4) and will be examined with elected claim 4.

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3. Claims 1-3, 5, 6 and 8 (and SEQ ID NO:s 2, 6 and 8) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

The Abstract needs to be revised in order to reflect the elected subject matter.

4. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 4 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention.

Applicants claim a plasmid isolatable from *C. thermoaminogenes* which comprises a gene coding for a rep protein having the amino acid sequence of SEQ ID NO:4 or a sequence having 99% homology (or more) to said sequence and has a size of about 4.4kb or a derivative thereof. Applicants define a derivative thereof as a plasmid composed of a part of the plasmid of the present invention, or the part of the instant plasmid and another DNA sequence; "the part" being a part containing a region essential for the autonomous replication of the plasmid. A derivative therefore reads on any plasmid containing any gene (rep gene) or portion of any gene on said plasmid essential for the autonomous replication of the plasmid. The claims read on a genus of plasmids comprising, at least, a portion of a rep gene (SEQ ID NO:4) which is essential for autonomous replication of the plasmid. Applicants provide a written description of a rep gene (SEQ ID NO:4) and three sequences encoding rep genes (all isolated from various strains of *C. thermoaminogenes*) which are 99% identical to SEQ ID NO:4.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show

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applicant was in possession of the claimed genus. In the instant case, applicants provide no correlation between the structure of the rep proteins and their function(s) involving DNA replication. Neither applicants nor the prior art disclose motifs in the rep protein which are essential for DNA replication and given the lack of said disclosures, the skilled artisan would be unable to identify portions of the rep protein which are essential for the recited activity of the protein. The skilled artisan would therefore would not conclude that applicants were in possession of the claimed genus. It is also noted that it is unclear if the rep gene is the only sequence essential for autonomous replication of the recited plasmid in a host. If additional sequences are essential for autonomous replication of the plasmid, applicants have provided no disclosure of said sequences.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be sent directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
April 13, 2003

  
DAVID GUZO  
PRIMARY EXAMINER